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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,270	04/25/2007	Reto Luginbuehl	00366.000211.	3143

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EXAMINER	
MONTANO, MELISSA ANN	
ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
10/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,270	LUGINBUEHL ET AL.	
	Examiner	Art Unit	
	MELISSA MONTANO	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-59 and 65-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-59 and 65-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 June 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed 6/12/2009 has been entered. Claims 46-59 and 65-90 are currently pending in this application. Claims 60-64 are canceled. The previous objection to the drawings is withdrawn in light of applicant's amendments to the drawings. The previous rejections under 112 2nd paragraph are withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 46-59 and 65-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,626,950 B2 to Brown et al. (Brown) in view of US Patent No. 5,141,510 to Takagi et al. (Takagi).

Regarding at least claims 46-47, 50-51, 54-57, 65-69, and 89-90

Brown teaches a prosthetic implant having a tissue scaffold component and a fixation component that is useful in the repair/regeneration of defects present at junction sites such as articular or meniscal cartilage (col. 3, lines 13-30). The scaffold component (triphasic prosthetic device; 20) is a multi-layer composite structure having a polymeric phase (superficial layer; 22) and a ceramic phase (base component; 24), which are mechanically interlocked at an interphase region (body component; 26) that exhibits a microporous polymer foam (col. 3, lines 49-50). The examiner asserts that the

microporous polymer foam interphase region (body component; 26) necessarily meets the limitations of a solid block of polymer with channels wherein said solid polymer is porous, as claimed by applicant. Further, Brown teaches that porosity is provided by leachable inclusions, molds with pore forming pins, or drilling (col. 6, lines 56-60). The examiner asserts that these methods of forming pores/channels are known in the art and necessarily constitute at least one of mechanical, physical, and chemical methods of forming channels in a solid polymer, as claimed by applicant.

The features of the scaffold in accordance with the invention of Brown can be tailored to suit a particular application by selecting the appropriate ceramic, polymer and conditions for lyophilization of the polymer to obtain one or more of the following properties: (1) interconnecting polymer foams attached to the porous ceramic (2) a variety of porosities ranging from about 20% to about 98% for the polymer foam (3) a gradient in the pore size between the polymer and ceramic; (4) channels that run through the porous polymer foam for improved cell invasion, vascularization, and nutrient diffusion; and (5) micro-patterning of pores or the addition of other polymer structures on the surface of the polymer for cellular organization or to limit cellular invasion (col. 4, lines 1-14).

Each of the polymeric phase (fiber layer; 22), ceramic phase (base component; 24), and interphase region (body component; 26) have pores (23, 25, and 27) with an open cell structure (col. 4, lines 28-34). The examiner asserts that the porous polymer matrix of the interphase region (body component; 26) inherently includes a number of highly oriented hollow bodies and/or oriented tubes, such as the pores shown extending

through this phase of the implant. Further, there would inherently be a space between the tubes (pores) that is empty or filled with substance, as claimed by applicant.

Brown also teaches that the ceramic phase (base component; 24) may be composed of magnesium calcium phosphates, calcium carbonates, bioglasses, and mixtures therefore. Alternatively, the ceramic phase (base component; 24) may be in the form of a porous polymer matrix with inclusions of short ceramic fibers or particulates (col. 6, lines 54-56). The examiner asserts that these materials taught by Brown inherently meet the limitation of the base component comprising a bone substitute material that is a synthetic ceramic that comprises at least one of metallic, semimetallic components and non-metallic components, preferably magnesium, silicon, sodium, potassium, strontium, and lithium, and further that the material is a composite material comprising at least two different components, as claimed by applicant.

Further, Brown teaches that the polymeric phase (superficial layer; 22) may be either a natural or synthetic polymer, or combinations of both. Natural biopolymers include collagen, elastin, etc. (col. 6, lines 61-65). The examiner asserts that at least the natural biopolymers taught by Brown inherently meet the limitation of the superficial layer comprising randomly oriented fibers, as fiber is defined as collagen, reticulin, elastin, etc. on page 3 of applicant's specification.

However, Brown does not explicitly teach that more than 50%, or more than 90% or 95%, of the highly oriented hollow bodies of the polymeric hollow body component are aligned perpendicularly to a plane of an articulating surface of the base component

or that a lateral distribution of the hollow bodies is homogenous, random, or in a specific pattern.

It would have been obvious to one having ordinary skill in the art at the time of the invention to try these types of orientation of hollow bodies, particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 6 of applicant's specification that states that fibers may change alignment direction). Further, claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit the claim to a particular structure, for example including "wherein" clauses and functional language. See MPEP 2111.04.

Regarding at least claims 48-49, 52-53, and 76-78

Brown teaches the invention substantially as claimed according to claims 46 and 47. The polymer phase (superficial layer; 22) may have a porosity/liquid-absorbing capacity of about 80 to about 95% with pores that are of the order of 100 μm (about 80 to about 120 μm). It is expected that chondrocytes will invade the zone. The ceramic phase (base component; 24) may have larger pores (about 250 to about 400 μm) and a porosity/liquid-absorbing capacity in the range of about 50 to about 95% which is structurally compatible with cancellous bone. Brown teaches that the interphase region (body component; 26) resembles the structural transition between cartilage and bone.

Therefore, it is understood that the size of the pores (inner channel diameter) located in the interphase region are necessarily between the sizes of the pores located in the ceramic phase (base component; 24) and the polymer phase (superficial layer;

22), resulting in a pore size of approximately about 120 to about 250 μm and thus meeting the limitation of an inner channel diameter of the hollow bodies of the body component in a range of 500nm to 500 μm, more specifically in a range of 5 μm to 150 μm, as claimed by applicant.

Also, the examiner asserts that the porosity taught by Brown necessarily meets the limitation that at least one of the randomly oriented fibers, the polymeric hollow body component, and the base component, has a liquid absorbing capacity in a range of 0.1% to 99.9%, more specifically in a range of 20.0 to 95.0%. The examiner further asserts that it would have been obvious to one having ordinary skill in the art to include that the liquid is at least one of an aqueous media and a body fluid, as claimed by applicant.

However, Brown does not explicitly teach that the inner channels/pores have a wall thickness ranging between 1 nm and 500 μm or between 100 nm and 250 μm.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Brown to specify a range of wall thickness of the inner channels/pores, particularly in view of the lack of any disclosed criticality of the claimed limitations. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claims 58-59 and 70-75

Brown teaches the invention substantially as claimed according to claim 46. Brown also shows that the shape of the ceramic phase (base component; 24) is round,

cylindrical, or conical (figs. 1 and 2) and that the polymeric phase (superficial layer; 22) is formed by the uppermost end of the interphase region (body component; 26), as claimed by applicant.

However, Brown does not explicitly teach a height of the hollow bodies being 50 μm to 10 mm or between 100 μm and 2 mm, a diameter of the base component ranging between 4 and 20 mm, a height of the base component being 1 to 30 mm or 1 to 10 mm, or a thickness of the superficial layer of 1 nm to 5 mm or 10 μm to 2 mm.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the scaffold of Brown to include these limitations in order to provide a prosthetic implant that would properly fit the size of defect in need of repair, particularly in view of the lack of any disclosed criticality (see pages 10 and 13 of applicant's specification). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claim 79

Brown teaches the invention substantially as claimed according to claim 46. However, Brown does not explicitly teach that the hollow body component is cross-linked.

The examiner asserts that the hollow body component of Brown is inherently cross-linked since a cross-link is defined as a bond that links one polymer chain to another and since the materials taught by Brown, including synthetic and natural polymers, inherently constitute polymer chains.

Regarding at least claims 80-84 and 86

Brown teaches the invention substantially as claimed according to claim 46. Also according to Brown, therapeutic agents (externally added component/pharmaceutical compound) may also be delivered via the implant (col. 10, lines 40-41). The examiner asserts that these therapeutic agents would necessarily constitute a chemical substance, particularly in view of the lack of criticality of this limitation in applicant's specification. The therapeutic agents taught by Brown include antibiotics and growth factors. Brown also teaches that cells including osteoblasts, chondrocytes, autogeneous, allogenic, and xenogenic, may be applied or seeded into the scaffold (prosthetic device; 20).

Regarding at least claim 85

Brown teaches the invention substantially as claimed according to claim 46. Brown teaches that the interconnecting pores of the device facilitate the transport of nutrients and/or invasion of cells into the scaffold, facilitating the ingrowth of tissue and more closely mimicking naturally occurring tissue junctions (col. 3, lines 55-58). The examiner asserts that it would be obvious to one having ordinary skill in the art at the time of the invention that blood or any fraction thereof would be present throughout the scaffold, and particularly in the ceramic phase (base component; 24), as claimed by applicant.

Regarding at least claims 87-88

Brown teaches the invention substantially as claimed according to claim 46. However, Brown does not explicitly teach a cell barrier layer or a cell selective barrier layer provided between the body component and the base component.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention of Brown to specify the inclusion of a cell selective barrier in order to limit cell invasion, as taught by Brown (col. 4, lines 11-14).

Response to Arguments

4. Applicant's arguments with respect to claims 46, 47, 52, 65, 67-69, 76, 79, 81, and 83 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738